

# Blood bag cassette for cryostorage of blood samples has reception space for blood bag defined between 2 cooperating cassette plates

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
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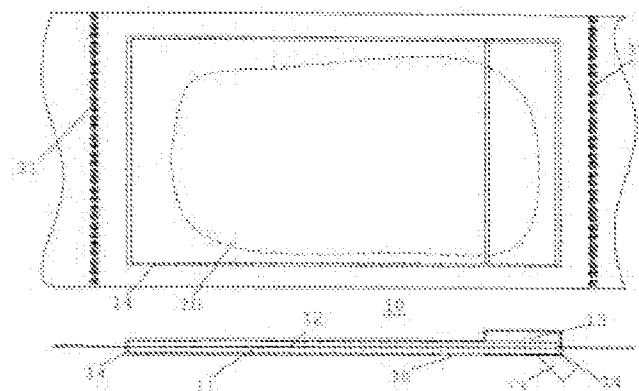
**Cited documents:**

 DE4437091 (A1)

 US4994021 (A)

## Abstract of **DE 10056181 (C1)**

The blood bag cassette (10) has 2 cassette plates (11,12), together defining a reception space for a blood bag (20), when fitted within a flexible outer sleeve (30), acting as a holder for the cassette plates. The flexible outer sleeve can be provided by a bag which has an evacuation connection (33), allowing it to be evacuated after insertion of the cassette plates. An Independent claim for a method for providing a cryostored blood sample is also included.



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The invention concerns a blood bag cartridge, in particular the organization of a blood bag cartridge for the Kryokonservierung of blood tests, a blood Kryokonserve and procedure for the production and/or. Organization such blood bag of a cartridge or blood Kryokonserve.

The manual production of blood Kryokonserven from full donations of blood is well-known. In accordance with the schematic illustration in Fig. 2 with the well-known technology a plastic bag 20 is inserted ' with the donation of blood into blood bag a cartridge 10 '. The conventional blood bag cartridge 10 shown in Drauf and side views ' is formed 12 by two cartridge plates 11 ', ', which form an admission for the blood bag 20 ' in the compound condition. The cartridge plates consist usually of metal and are equipped additionally with ( ) means not shown for handling with the Kryokonservierung. The cartridge plates form a container, which gives when freezing a defined form to the blood bag and which donation of blood in the frozen condition protects from mechanical damages. The form of the container is in such a way laid out that the donation of blood in the blood bag 20 possesses ' a schichtförmige shape, which a fast, homogeneous Durchfrieren of the unit of stored blood ensures.

The cartridge plates 11 ', 12 ' of the conventional blood bag cartridge 10 ' are held together with a mounting plate mechanism 30 ', which covers two laterally bolted clips (or handle) 31 ', 32 '. To the Kryokonservierung of a donation of blood this is inserted in the blood bag 20 ' between the cartridge plates 11 ', 12 '. Afterwards the clips 31 ', 32 ' are put on and bolted. Subsequently, the actual Kryokonservierung takes place via immersing blood bag cartridge 10 ' into a nitrogen bath.

The conventional blood bag cartridge 10 ' possesses the following disadvantages. The clips 31 ', 32 ' are unfavorable regarding the handling of the cartridge and regarding the preservation result. It places one, in particular with view of an automation of the Kryokonservierung, to relatively large expenditure, the clips 31 ' to attach and bolt 32 ' reliably and position. The moreover one the homogeneity of the freezing procedure is impaired by the clips 31 ', 32 '. The parts present between the clips disturb the homogeneity of the freezing procedure, which affects unfavorably the chances of survival of the kryokonservierten red blood corpuscles. Unfavorable it is also that the handling of the blood bag cartridge can be made more difficult with withdrawal of the unit of stored blood in the frozen condition because of frozen-over clips.

A further disadvantage of the conventional blood bag cartridge 10 ' exists in reduced security during the handling of the blood bag. Becomes this bspw. when inserting into the cartridge ' or when freezing by a spanning hurts 10, then it can come to thawing out to the withdrawal or complete loss of the donation of blood. In addition parts of the Kryokonservierungsanlage with the withdrawing blood can be contaminated. Such contamination is to be excluded in particular in the context of an automated blood bank absolutely.

A further disadvantage actually concerns the conventional blood bag cartridges 10 '. Since both the cartridge plates 11 ', 12 ' and the clips 31 ', 32 ' exist usually made of metal, it comes with the freezing procedure in liquid nitrogen to the suffering frost phenomenon. To this phenomenon it comes at the contact area of two non-gaseous materials if the temperature of the warmer material (here: the cartridge plates for instance at ambient temperature) the boiling temperature of the colder material (here: liquid nitrogen, TS = -195,8 DEG C) far exceeds. On the exterior of the cartridge plates forms a thin warm-damming layer from vaporous nitrogen, which a fast and homogeneous Durchfrieren of the donation of blood obstructs.

From EP 0,457,782 a blood bag cartridge is well-known for blood tests, with which the cartridge plates with laterally attached clips are go-aged. This cartridge possesses however also the disadvantages mentioned regarding the handling of the lateral clips, in particular with the automated enterprise, and regarding the training suffering frost of the phenomenon.

In DE-OS 44 37 091 a freezing container is described for the low freezing of suspensions of living cells in plastic bags. The container carries a micro-porous layer for the improvement of the heat transfer of the environment on the container. The micro-porous layer is to prevent in particular the suffering frost phenomenon. It was however shown that this intended effect is only reduced obtained. The moreover one the micro-porous layer represents a disadvantage regarding the container cleaning.

Further cartridge and framework mounting plates for blood bag freezing canned goods are from DE-PS 197 46 610, US-PS 4994021, WHERE 95/09597 and WHERE 97/31609 admit.

The task of the invention is it to make improved blood bag a cartridge available for the Kryokonservierung of blood tests with which the disadvantages mentioned of conventional cartridges to be overcome to be able. In particular an easily manageable mounting plate for the cartridge plates is to form the blood bag according to invention cartridge, to make a high security possible while handling the donations of blood and to improve the homogeneity of the freezing procedure. The task of the invention is it also to indicate an improved procedure for the production of blood Kryokonserve which permits in particular a homogeneous freezing and a safe handling Kryokonservierungsanlagen automated by donations of

blood in.

These tasks are solved with a blood bag cartridge, a blood Kryokonserve and a procedure with the characteristics of the patent claims 1, 8 and 9. Favourable execution forms of the invention result from the dependent requirements.

The philosophy of the invention is it to provide a blood bag cartridge, which actually exhibits like the conventional cartridge two cartridge plates, with a new mounting plate mechanism which is formed by a flexible outer hull, with which the cartridge plates are held together. The outer hull preferably consists of a plastic foil, which encloses the cartridge plates. In accordance with a first execution form of the invention the outer hull is formed by a bag surrounding the cartridge plates. With a second execution form of the invention each cartridge plate is arranged in its own disk covering, whereby the disk coverings at their outside edges are so interconnected that they together form the outer hull, which holds the cartridge plates together.

The transition of the conventional clips or screws for the mounting plate of the cartridge plates with the flexible outer hull possesses a set of advantages. Thus the mounting of the mounting plate mechanism in form of a flexible outer hull, in particular in automated Kryokonservierungsanlagen, is substantially simplified. The outer hull encloses the entire cartridge, so that without further measures an inhomogenous force practice is avoided on the cartridge plates. Inhomogenous temperature gradients when freezing or thawing out are avoided. Finally the flexible outer hull forms also a safety device against possible withdrawing of a blood test from the blood bag. If the outer hull from a plastic material is formed, also the problem mentioned of the suffering frost phenomenon is solved. On the plastic surface no steam layer forms.

In accordance with a preferential execution of the invention the outer hull forms, if necessary, in cooperation with the cartridge plates, an evacuated bag or an evacuated cartridge. Under effect of the outside air pressure is with the o. g. first execution form the outer hull evenly on the cartridge plates up, so that these are squeezed together. With the o. g. the whole cartridge is evacuated second execution form, so that the cartridge plates are squeezed together directly by the outside air pressure.

The subject of the invention is also a procedure for the production of a blood Kryokonserve, which is characterised in particular by the fact that a blood bag with a donation of blood between the cartridge plates of a blood bag cartridge is arranged and used for their mutual adjustment a flexible outer hull. The flexible outer hull becomes with the o. g. first execution form over the cartridge plates touched, so that these hold together. With the o. g. second execution form the outer hull is formed for z by the cartridge coverings, those at their edges for mutual adjustment with one another. B. to be stuck together or welded. It is particularly favourable, if before freezing a evacuation of the outer hull and/or. the cartridge takes place.

Further advantages and details of the invention become evident from the description of the attached designs. Show:

Fig. 1 schematic Drauf and side views of a blood bag cartridge according to invention, and

Fig. 2 schematic Drauf and side views of a conventional blood bag cartridge (state of the art).

In accordance with the first execution form of the invention a blood bag cartridge consists 10 of two cartridge plates 11, 12 and the flexible outer hull 30 (see Fig. 1). The cartridge plates 11, 12 become by Metallbleche (z. B. from aluminum or copper) with laterally bent upward edges in an educated manner. One of the cartridge plates 11, 12 possesses smaller extents, so that in the compound condition to one on the other-assign the edges of the cartridge plates interlink and the edges of the smaller cartridge plate on the internal soil of the larger cartridge plate rest upon. In the compound condition by the cartridge plates an admission (container) for a blood bag 20 is formed, whose surface area is formed by the surface of the cartridge plates and its depth by the height of the bent disk edges. For the admission of a freeze-finished erythrocyte suspension (about 400 ml from the erythrocyte concentrate from a full donation of blood, shifted with a Kryoadditiv) the internal distance of the cartridge plates can bspw. 7 mm amount to.

At an end one of the cartridge plates can be intended a projection/lead 13 with additional mechanisms for the handling of the blood bag cartridge 10, as she actually admits is. This is however no compelling characteristic of the invention. The cartridge 10 can be seized rather also without access to a separate projection/lead 13 and moved in a Kryokonservierungsapparatur.

As mounting plate mechanism is in Fig. 1 the flexible outer hull 30 intended. The outer hull 30 is partly drawn in with a small distance from the cartridge plates 11, 12 in the cutaway view for clarity reasons, rests upon the surface of the cartridge plates 11, 12 in practice however firmly. With the represented remark example the outer hull 30 is formed by a tubular sheeting, which is at the lateral ends of the cartridge plates 11, 12 gas and liquid locked. The tubular sheeting is bspw. along scored the drawn lines welds 31, 32 (welding seams).

The outer hull exists bspw. from flexible PU foil, with a thickness of z. B. 0.02 to 0.04 mm. Alternatively in addition, other suitable plastic foils can be used, be held together sufficiently surely and firmly with those the cartridge plates 11, 12. Alternatively the outer hull according to invention consists of a flexible, rubber-like flexible tubular sheeting, which can be pulled over the closed cartridge and which pulls plates together. Evacuating of the outer hull would not be necessary in this case.

In accordance with a modified organization of the blood bag cartridge according to invention the outer hull does not become 30 by a tube piece, but by an at least on one side closed plastic bag in an educated manner, whose cut and mass straight are so selected that the compound cartridge plates 11, 12 with the blood bag 20 are introduced into the bag and kept positive in this. If in the Kryokonservierungsanlage and a blood bank the spatial orientation of the bag remains, it is not compellingly necessary to lock these. Otherwise can as during the representation in Fig. 1 a welding of the bag intended its.

In accordance with a preferential execution form of the invention the outer hull 30 is evacuated. For this is the outer hull if necessary, with an outlet duct 33 (in Fig. 1 broken drawn) equipped. After bringing in the cartridge plates with the blood bag in bag or schlauchförmige outer hull and their catch the inside of the covering is evacuated on a slight negative pressure, so that the outside air pressure presses the outer hull on the cartridge plates.

For the acceleration of the evacuation it can be intended according to invention that the exteriors of the cartridge plates possess a surface texture, which guarantees the removal of air from the outer hull also with closely resting upon outer hull. The structuring becomes preferably by a groove rotating at the outer edge of the cartridge plates 14 (see Fig. 1) formed. (Exhaust) the groove 14 and the outlet duct 33 are relatively to each other in such a way positioned that the outlet duct 33 over the groove 14 is arranged. The groove can run also on the exteriors with behaviour of the edge.

The outlet duct 33 can be used simultaneously for its function as connection part with a pumping mechanism also as seizing or shim for the handling of the cartridge in a Kryokonservierungsanlage.

In accordance with a further execution form of the invention the cartridge plates are enclosed in each case by a disk covering (not represented). At each cartridge plate an outside, the cartridge plate completely surrounding covering from plastic material is intended. Each disk covering possesses a larger surface than the cartridge plate taken up in each case. On all sides of the cartridge plates the disk covering exceeds over the disk edge. The mutual connection of the edges of the disk coverings closed-up in the compound condition takes place bspw. by welding. Alternatively, in particular if it does not depend on the evacuation of the casing, the edges of the disk coverings can be coupled also with a zipper connection.

In accordance with a further modification than outer hull according to invention also only a disk covering can be intended, which takes up both cartridge plates planar next to each other lying. In the compound condition the cartridge plates are arranged one on the other lying. In this condition the then still free wheels of the disk covering are stuck together with one another or shut.

According to invention it can be also intended that at least one edge of the disk covering with an edge neighbouring in the folded up condition of the cartridge according to kind of flexible bellows are connected. For bringing in the blood bag the cartridge plates are pressed apart under expansion of the bellows (bellows). After inserting the blood bag firm welding of the outer hull takes place, so that the cartridge plates are firmly closed-up held.

Also with the education of the outer hull according to invention from or two disk coverings a evacuation of the outer hull can be intended, as it was described above.

A special advantage of the invention shows up with view according to invention of the freezing results attainable with the blood bag cartridge. As parameters for the evaluation of the success of a freezing procedure the haemolysis rate of the again thawed out Erythrozyten can be used. The haemolysis rate indicates, which percentage of the examined cells by the freezing procedure were damaged. It was shown that with a conventional cartridge (without the outer hull according to invention) medically not tolerable haemolysis rates arise. In the case of employment of the outer hull according to invention, in particular with the organization with completely included cartridge plates a substantial improvement of the haemolysis values results, whereby Kryokonserven can be manufactured not only economically, but also with medically tolerable haemolysis results.

A further advantage of the invention consists of the fact that with evacuation of the outer hull the cartridge plates do not have to be aligned in particular separately.

The characteristics of the invention revealed in the managing description, the requirements and the designs can be both individually and in arbitrary combination for the implementation of the invention in its different arrangements of importance.